REMARKS

In the Office Action dated October 3, 2007, the Examiner alleges that this application contains the following groups of inventions that are allegedly independent and distinct from each other according to 35 U.S.C. § 121:

Group I, claims 1-11, with the technical feature of a virus-like particle comprising i) a fusion protein comprising a polypeptide of interest and a hepadnavirus large envelope polypeptide; and ii) a hepadnavirus small envelope polypeptide.

Group II, claims 12-21, with a technical feature of a polypeptide comprising a polypeptide of interest and a particle-associating portion of a large envelope polypeptide.

Group III, claims 22, 24-30 (in part) and 40-41 (in part), with a technical feature of a nucleic acid molecule comprising sequences that encode a polypeptide of interest and a particle-associating portion of a large envelope polypeptide.

Group IV, claims 23, 24-30 (in part) and 40-41 (in part), with a technical feature of a nucleic acid comprising sequences that encode i) a fusion protein comprising a polypeptide of interest and a particle-associating portion of a large envelope polypeptide; and ii) a hepadnavirus small envelope polypeptide.

Group V, claims 31 and 33-39 (in part), with a technical feature of a nucleic acid encoding a particle-associating portion of a large envelope polypeptide and one or more cloning sites.

Group VI, claims 32 and 33-39 (in part), with a technical feature of a nucleic acid encoding i) a particle-associating portion of a large envelope polypeptide and ii) a small envelope polypeptide and comprising one or more cloning sites.

Group VII, claims 42-44, with a technical feature of delivering a protein of interest by administering to a subject or cell a virus-like particle comprising the protein of interest and an avian hepadnavirus large envelope polypeptide.

Group VIII, claim 45, with a technical feature of making a virus-like particle comprising a protein of interest, a particle-associating portion of a large envelope polypeptide of an avian hepadnavirus, and a small envelope polypeptide.

In order to be fully responsive to the Examiner's requirement for restriction under PCT Rule 13.1, Applicants provisionally elect, with traverse, to prosecute the subject matter encompassed by Group II, comprising claims 12-21. However, it is believed that the following remarks, in conjunction with the foregoing amendments effectively traverse the restriction requirement.

Claims 1-3, 7-10, 12-13, 16-23, 26-28 and 42 have been amended. Claims 1-30 and 40-45 are directed to the following conceptually linked embodiments of the invention:

- Amended claims 1-11 encompass virus-like particles ("VLPs") comprising fusion polypeptide containing a particle-associating portion of an avian hepadnavirus L envelope protein.
- Amended claims 12-21 encompass an isolated or recombinant polypeptide which includes a particle-associating portion of avian hepadnavirus envelope protein for use in the assembly of (VLPs).
- Amended claims 22-30 encompass a nucleic acid molecule encoding a fusion protein for use in marking a VLP.
- Claims 40-45 encompass cells and methods of preparing or delivering avian hepadnavirus VLPs.
- Claims 31-39 are canceled, thereby removing the claims of Groups V and VI from consideration.

It is respectfully submitted that claims 1-30 and 40-45, encompassed by Groups I to IV and VII to VIII share the same corresponding special technical features, and therefore, relate to a single inventive concept. Further, the specific shared special technical feature does indeed provide a contribution over the teaching of Kuroda et al. Accordingly, it is respectfully

requested that the restriction requirement be withdrawn and that the claims of Groups I to IV and VII to VIII be examined together.

Special Technical Feature

"Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding "special technical features". The expression "special technical features" is defined in Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. MPEP, Administrative Instructions Under the PCT, Annex B.

The present invention provides VLPs comprising a particle associating portion of avian hepadnavirus large enveloep protein, wherein the VLPs are prepared using recombinant technology and are immunogenic when administered to a mammal (Specification page 52, Example 14). Accordingly, the claims of group I are drawn to a VLP comprising a fusion protein comprising a polypeptide of interest and a particle associating portion of a large avian hepadnavirus envelope polypeptide, while the claims of Goup II are drawn to the fusion protein itself, thereby sharing the same special technical feature. The claims of Groups VII and VIII respectively encompass methods directed to using and making VLPs comprising a polypeptide of interest and a particle associating portion of a large avian hepadnavirus envelope polypeptide. Accordingly, all claims of Groups I, II, VII and VIII share the same special technical feature, and should be examined together.

Further, the claims of Groups III are directed to nucleic acids encoding nucleic acid molecule comprising sequences that encode a polypeptide of interest and a particle-associating portion of a large envelope polypeptide. The claims of Group IV encompass nucleic acids comprising sequences that encode i) a fusion protein comprising a polypeptide of interest and a

particle-associating portion of a large envelope polypeptide; and ii) a hepadnavirus small envelope polypeptide. These groups of claims encompass nucleic acids encoding the fusion polypeptide that comprises the shared special technical feature. Encoding the fusion polypeptide renders the nucleic acids of Groups III and IV useful in methods of making and using the shared special technical feature. Therefore, it is respectfully submitted that the claims of Groups I, II, III, IV, VII and VIII, should be examined together.

Contribution Over the Prior Art

In the Office Action of October 3, 2007, the Examiner alleges that the claimed subject matter is not distinguishable over that disclosed by the Kuroda reference. Specifically, Kuroda teaches a fusion polypeptide where the chicken lysozyme signal sequence, C-SIG is fused to the amino-terminus of the mammalian L protein of Hepatitis B Virus (HBV).

Kuroda does not teach a VLP comprising a fusion polypeptide comprising a polypeptide of interest and a particle associating portion of an avian hepadnavirus large envelope polypeptide (L) or a functional derivative and an avian hepadnavirus small envelope (S) polypeptide or a functional derivative. Further, Kuroda does teach or suggest a polypeptide of interest as defined on page 19, line 1, of the specification, wherein the polypeptide of interest is one that is delivered to a subject as part of a virus-like particle. Kuroda's C-SIG is not encompassed by this definition of a polypeptide of interest. The C-SIG functions as a signal peptide to cotranslationally target the C-SIG-L polypeptide to the ER (endoplasmic reticulum), thereby enhancing the L protein's incorporation into VLPs. However, it is known that signal peptides are generally cleaved off of the proteins during insertion into the ER and are not part of the mature protein that is exported from the cell. Further, in contrast with the Applicants' VLPs

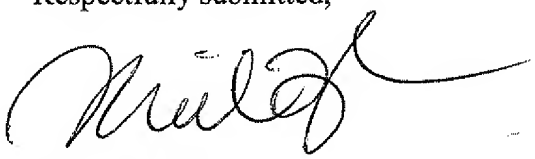
based on avian hepadnavirus envelope proteins, Kuroda's VLPs are not shown to be useful vehicles for presenting a polypeptide of interest to a subject. Accordingly, the Applicants' invention clearly make a contribution over the prior art.

In sum, it is respectfully suggested that the foregoing remarks and claim amendments are sufficient to traverse the restriction requirement. All amended claims share a special technical feature relating to the structure of avian hepadnavirus fusion polypeptides in VLP assembly and export. Further, the claimed particles have been shown to be functional, whereas those in the art, e.g., Kuroda have not.

Accordingly, it is respectfully requested that the restriction requirement be withdrawn and that claims 1-30 and 40-45 be examined together.

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



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